DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region

D1179B

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (201) 331-2910

February 10, 1997

WARNING LETTER

RELEASE

REVIEWED BY: C.O. 2/12/97 DATE

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED
Mr. Praful Raja, President
Diagnostic Specialties, Inc.
4 Leonard Street
Metuchen, New Jersey 08840

FILE NO.: 97-NWJ-18

Dear Mr. Raja:

During an inspection of your firm located at the above address between January 13 and January 22, 1997, our investigator determined that your firm manufactures in-vitro diagnostic test kits known as EnZIP Microalbumin test kit and Pregna-Cert pregnancy test kit. In-Vitro Diagnostics are medical devices as defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that the IVD devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Device Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm failed to evaluate and determine the effect of product changes on the performance of the finished EnZIP Microalbumin test kits, prior to distribution. For example:

   A. The 50 ug/ml Human Serum Albumin (HSA) standard of the EnZIP Microalbumin test kit, lot #070062, manufactured October 30, 31, 1996, failed to meet your finished product percent inhibition specification of [redacted]. During final QC testing, the percent inhibition specification for the 50 Standard was revised to [redacted]

   B. Percent inhibition of the 50 Standard (enzyme conjugate), lot #070962, QC tested on October 18, 1996, noted a result of [redacted], which failed to meet your specification of [redacted]

C. According to your current (July 1995) product insert, the change in incubation times and temperatures for the EnZIP Microalbumin test kit, were reduced from 30 minutes to 15 minutes.

D. A decrease in the diluted enzyme conjugate stability from 30 days to 7 days when stored at 2-8°C.

2. Your firm failed to have change control documentation justifying the reason for a change, the person reviewing, and approving a product change, for the EnZIP Microalbumin test kit. For example:

A. The finished microalbumin test kit, lot #070062, percent inhibition specification change for the 50 Standard from [redacted] initially, to the present specification of [redacted]

B. Stability changes for the reagents and time/temperature requirement changes for the test procedure, as stated in the test kit's current product insert, dated July 1995.

3. Your latest EnZIP Mircoalbumin product revisions were not made a part of your current Device Master Record (DMR). For example:

A. An increase in the diluted wash buffer stability from 9 months to 12 months when stored at 2-8°C.

B. The change in incubation times and temperatures for the EnZIP Microalbumin test kit, reduced from 30 minutes to 15 minutes, according to your July 1995 product insert.

C. A decrease in the diluted enzyme conjugate stability from 30 days to 7 days when stored at 2-8°C.

4. Human Serum Albumin (HSA) 0 ug/ml and 50 ug/ml standards, lot #070362, failed to met Optical Density (O. D.) specifications.

5. Your firm failed to qualify the [redacted] microplate processing instrument, as well as, the [redacted] Control Software and the [redacted] Software, for their intended use.

6. Your firm failed to maintain raw test data regarding in-process microalbumin assay testing for bulk HSA standards of the EnZIP Microalbumin test kits.

7. Your firm's storage control procedures do not assure that the labeled storage temperatures for the bulk Microalbumin reagents; the finished Microalbumin kits, and the PregnaCert kits are met, since there is no continuous monitoring of your refrigeration units.

Additionally, it was noted that your firm failed to set acceptable ranges for all lots of EnZip MicroAlbumin test controls manufactured by your firm.

Furthermore, this inspection uncovered that your EnZip MicroAlbumin finished test kit, lot #070062, and individual reagent lots included with the finished product, were labeled and released with the incorrect expiration date. We understand that you are currently conducting a voluntary recall of this product from your accounts. If you have not already done so, we request that you contact our Recall and Emergency Coordinator, Mr. Louis Rosen, (201) 331-2913, involving this recall and any future recalls.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the good manufacturing practice regulations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against the award of contracts for affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Boulevard, Parsippany, New Jersey 07054, Attention: Vincent P. Radice, Compliance Officer.

Very truly yours,

STEVEN MASIELLO
Acting District Director
New Jersey District Office

VPR:slw